

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION

KIMBERLY K. PARKER and RANDY PARKER,	)	CIVIL ACTION NO. 3:09-cv-02581-JZ
	)	
Plaintiffs,	)	JUDGE JACK ZOUHARY
	)	
v.	)	
	)	
ETHICON, INC. and JOHNSON & JOHNSON COMPANY,	)	<b><u>ANSWER AND SEPARATE</u></b>
	)	<b><u>DEFENSES OF DEFENDANT</u></b>
Defendants.	)	<b><u>JOHNSON &amp; JOHNSON TO</u></b>
	)	<b><u>PLAINTIFFS' COMPLAINT</u></b>
	)	
	)	<b><u>JURY TRIAL DEMANDED</u></b>

Defendant Johnson & Johnson (improperly captioned as “Johnson & Johnson Company”), by and through counsel, for its Answer to Plaintiffs’ Complaint, states as follows:

**COUNT ONE**

1. Johnson & Johnson lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 1 of Plaintiffs’ Complaint, and therefore denies the same.

2. In response to Paragraph 2 of Plaintiffs’ Complaint, Johnson & Johnson admits that Ethicon, Inc. is the manufacturer, marketer, and seller of the Gynecare Prolift Pelvic Floor Repair System and Gynecare TVT-Secur. Johnson & Johnson does not design, manufacture, market, distribute or sell the Gynecare Prolift Pelvic Floor Repair System, Gynecare TVT-Secur, or any other product. Johnson & Johnson denies the remaining allegations of Paragraph 2 of Plaintiffs’ Complaint.

3. Johnson & Johnson denies the allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Johnson & Johnson denies the allegations contained in Paragraph 4 of Plaintiffs' Complaint.

5. Johnson & Johnson denies the allegations contained in Paragraph 5 of Plaintiffs' Complaint.

### **COUNT TWO**

6. Johnson & Johnson lacks sufficient knowledge or information to form a belief as to the truth of the allegation contained in Paragraph 6 of Plaintiffs' Complaint as to Plaintiff Randy Parker's relationship to Plaintiff Kimberly K. Parker, and therefore denies the same. Johnson & Johnson denies the remaining allegations contained in Paragraph 6 of Plaintiffs' Complaint.

### **AFFIRMATIVE/SEPARATE DEFENSES**

#### **FIRST SEPARATE DEFENSE**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

#### **SECOND SEPARATE DEFENSE**

Plaintiffs' claims are barred by the applicable statute of limitations, statute of repose, and/or the equitable doctrines of laches and estoppel.

#### **THIRD SEPARATE DEFENSE**

Johnson & Johnson hereby raises, asserts, and preserves its defense of lack of personal jurisdiction.

#### **FOURTH SEPARATE DEFENSE**

Johnson & Johnson hereby raises, asserts, and preserves its defense of improper venue.

**FIFTH SEPARATE DEFENSE**

Plaintiffs' Complaint has failed to name necessary and indispensable parties.

**SIXTH SEPARATE DEFENSE**

Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

**SEVENTH SEPARATE DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, may have been caused in whole or in part by Plaintiffs' own conduct, intentional acts, contributory negligence, assumption of risk, and want of care. (R.C. §§ 2307.22, 2315.32 *et seq.*)

**EIGHTH SEPARATE DEFENSE**

Some or all of Plaintiffs' claims are barred by the doctrine of superseding and/or intervening cause.

**NINTH SEPARATE DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, were due to allergic, idiosyncratic, or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, without any negligence or culpable conduct by Johnson & Johnson.

**TENTH SEPARATE DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, were caused in whole or in part by the acts (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more persons or entities over whom Johnson & Johnson exercised no control and for whom Johnson & Johnson is not legally responsible.

**ELEVENTH SEPARATE DEFENSE**

Plaintiffs' claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

**TWELFTH SEPARATE DEFENSE**

Plaintiffs' claims are barred by the learned intermediary doctrine, as codified by R.C. § 2307.76(C).

**THIRTEENTH SEPARATE DEFENSE**

Plaintiffs' claims against Johnson & Johnson are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the U.S. Food and Drug Administration and contained in Chapter 21 of the Code of Federal Regulations. See 21 U.S.C. § 301 et seq.; see also 71 Fed. Reg. 3922 (Jan. 24, 2006).

**FOURTEENTH SEPARATE DEFENSE**

Plaintiffs' claims are barred because Johnson & Johnson complied with all applicable state and federal statutes regarding the product in question including the requirements and regulations promulgated by the U.S. Food and Drug Administration and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiffs' claims are not barred, Johnson & Johnson is entitled to a presumption that the product in question is free from any defect or defective condition as the plans or design for the product or the methods and techniques of manufacturing, inspecting, and testing the product were in conformity with government standards established for the prescription drug industry that were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting, and testing the product were adopted.

**FIFTEENTH SEPARATE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the Federal Food, Drug, & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder.

**SIXTEENTH SEPARATE DEFENSE**

Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Johnson & Johnson and all its activities with respect to the subject product have been and are conducted under the supervision of the FDA.

**SEVENTEENTH SEPARATE DEFENSE**

Johnson & Johnson did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by lack of privity between Plaintiffs and Johnson & Johnson, and/or Plaintiffs' failure to give Johnson & Johnson timely notice of the alleged breach of warranty. Johnson & Johnson further specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code, as enacted in the State of Ohio and any other state whose law is deemed to apply in this case.

**EIGHTEENTH SEPARATE DEFENSE**

Plaintiffs' claims are barred by comments *j* and *k* to Section 402A of the Restatement (Second) of Torts.

**NINETEENTH SEPARATE DEFENSE**

Plaintiffs' claims are barred by Sections, 2, 4, 6(c), and 6(d) of the Restatement (Third) of Torts: Products Liability.

**TWENTIETH SEPARATE DEFENSE**

Plaintiffs' product liability claims are barred because the benefits of the relevant product outweighed its risks.

**TWENTY-FIRST SEPARATE DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

**TWENTY-SECOND SEPARATE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because Johnson & Johnson acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its product.

**TWENTY-THIRD SEPARATE DEFENSE**

Johnson & Johnson is entitled to set-off for all amounts paid, payable by, or available from collateral sources.

**TWENTY-FOURTH SEPARATE DEFENSE**

There is no causal relationship between Defendant's conduct and the injuries and damages alleged by Plaintiffs in the Complaint.

**TWENTY-FIFTH SEPARATE DEFENSE**

Plaintiffs impermissibly seek to impose liability on conduct protected from liability by the First Amendment to the United States Constitution and by the Constitution of the State of Ohio and any other state whose law is deemed to apply in this case.

**TWENTY-SIXTH SEPARATE DEFENSE**

Johnson & Johnson is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case.

**TWENTY-SEVENTH SEPARATE DEFENSE**

Plaintiffs' common law claims for relief are abrogated by R.C. § 2307.71(B).

**TWENTY-EIGHTH SEPARATE DEFENSE**

Plaintiffs' non-statutory common law product liability claims fail to state claims upon which relief can be granted under Ohio law because these claims have been abolished and/or superseded by Ohio's Product Liability Act, R.C. § 2307.71 *et seq.* These claims for relief should be stricken *sua sponte* as "insufficient claims" pursuant to Fed.R.Civ.Proc. 12(f).

**TWENTY-NINTH SEPARATE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of express and/or implied assumption of the risk as set forth in R.C. § 2307.711.

**THIRTIETH SEPARATE DEFENSE**

Plaintiffs' design defect claims are barred under R.C. §§ 2307.75(D) and (E) because the alleged risk of which they complain is unavoidable and/or an inherent characteristic of the products at issue which is a generic aspect of those products that cannot be eliminated without substantially compromising the usefulness or desirability of those products.

**THIRTY-FIRST SEPARATE DEFENSE**

Plaintiffs' inadequate warning claims are barred under R.C. § 2307.76(B) because the alleged risk of which they claim is open, obvious, and/or a matter of common knowledge.

**THIRTY-SECOND SEPARATE DEFENSE**

Plaintiffs' recovery, if any, must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or in part.

**THIRTY-THIRD SEPARATE DEFENSE**

A percentage of the tortious conduct that proximately caused the injury and damage claimed by Plaintiffs is attributable to one or more persons from whom the Plaintiffs do not seek recovery in this action. (R.C. § 2307.23(C))

**THIRTY-FOURTH SEPARATE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of *res judicata*, collateral estoppel, judicial estoppel, or by release of claims.

**THIRTY-FIFTH SEPARATE DEFENSE**

One or more of Plaintiffs' claims are barred by the tort reform provisions of Ohio law, including but not limited to, the limitations (caps) on compensatory damages set forth in R.C. § 2315.18.

**THIRTY-SIXTH SEPARATE DEFENSE**

Plaintiffs' claims against defendant Johnson & Johnson are barred because defendant Johnson & Johnson did not develop, manufacture, promote, or sell the product(s) at issue in this case.



**THIRTY-SEVENTH SEPARATE DEFENSE**

Johnson & Johnson hereby reserves the right to amend its answer to assert any other defenses, affirmative or otherwise, that may become available during discovery proceedings in this case.

**WHEREFORE**, having fully answered Plaintiffs' Complaint, Defendant Johnson & Johnson respectfully requests that this Court enter an Order dismissing Plaintiffs' Complaint with prejudice at Plaintiffs' costs and granting such other relief as it deems just and equitable.

Respectfully submitted,

s/Justin E. Rice

Rita A. Maimbourg (0013161)

Justin E. Rice (0080587)

TUCKER ELLIS & WEST LLP

1150 Huntington Building

925 Euclid Avenue

Cleveland, OH 44115-1414

Tel: 216.696.3219

Fax: 216.592.5009

E-mail: [rita.maimbourg@tuckerellis.com](mailto:rita.maimbourg@tuckerellis.com)

[justin.rice@tuckerellis.com](mailto:justin.rice@tuckerellis.com)

*Attorneys for Defendants Ethicon, Inc. and  
Johnson & Johnson*

**JURY DEMAND**

Defendant Johnson & Johnson hereby demands a trial by jury pursuant to Federal Rule of Civil Procedure 38(b), for all claims so triable, made up of the maximum number of jurors permitted.

*s/Justin E. Rice*

\_\_\_\_\_  
Rita A. Maimbourg (0013161)

Justin E. Rice (0080587)

TUCKER ELLIS & WEST LLP

1150 Huntington Building

925 Euclid Avenue

Cleveland, OH 44115-1414

Tel: 216.696.3219

Fax: 216.592.5009

E-mail: [rita.maimbourg@tuckerellis.com](mailto:rita.maimbourg@tuckerellis.com)  
[justin.rice@tuckerellis.com](mailto:justin.rice@tuckerellis.com)

*Attorneys for Defendants Ethicon, Inc. and  
Johnson & Johnson*

**CERTIFICATE OF SERVICE**

I hereby certify that on November 11, 2009, a copy of the foregoing *Answer to Plaintiffs' Complaint by Defendant Johnson & Johnson* was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Respectfully submitted,

s/Justin E. Rice

Rita A. Maimbourg (0013161)

Justin E. Rice (0080587)

TUCKER ELLIS & WEST LLP

1150 Huntington Building

925 Euclid Avenue

Cleveland, OH 44115-1414

Tel: 216.696.3219

Fax: 216.592.5009

E-mail: [rita.maimbourg@tuckerellis.com](mailto:rita.maimbourg@tuckerellis.com)  
[justin.rice@tuckerellis.com](mailto:justin.rice@tuckerellis.com)

*Attorneys for Defendants Ethicon, Inc. and  
Johnson & Johnson*